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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,243	05/02/2005	Tsutomu Sanaka	KPO-JMS-P1/SH-72/US	2622

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EXAMINER

ISSAC, ROY P

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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01/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,243

Applicant(s)

SANAKA ET AL.

Examiner

Roy P. Issac

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7-10,12,13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-5, 7-10, 12-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 10/15/07, wherein claims 2-3, 6, 11 and 14 have been cancelled and claims 1, 4, 8-10 and 13 have been amended. Claims 1, 4-5, 7-10, 12-13 and 15 are currently pending and are examined on the merits herein.

Rejections Withdrawn

In view of the cancellation of claims 2-3, 6, 11 and 14, all rejections made with respect to claims 2-3, 6, 11 and 14 in the previous office action are withdrawn.

Applicants' amendments to claims 8 and 9 removing multiple dependency overcomes the objection of claims 8 and 9 for improper multiple dependency.

Applicants' amendment to claim 4 inserting the range 0.5 to 1.5% w/v% overcomes the rejection of claims 4 under section 102(b), since Bartz et. al. only exemplify a concentrated taurine solution of 0.49% in example 1.

The following are new or modified rejections necessitated by Applicant's amendment filed 10/15/07, wherein the limitations in pending claims 1, 4, 8-10 and 13 as amended now have been changed. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 7/13/07, have been modified and are listed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartz et. al. (AU 615553; PTO-1449, dated 3/16/2005).

Bartz et. al. discloses solutions for intraperitoneal administration comprising taurine. (Page 1, Claim 1). Bartz et. al. further discloses compositions comprising taurine (4.9 g/l = 0.49 w/v%), sodium lactate (48 mmol/l), sodium chloride (5.785 g/l = 99 mmol/l), calcium chloride dihydrate (0.2573 g/l = 1.75 mmol/l), magnesium chloride (0.1017 g/l = 0.5 mmol/l) and a pH value of 5.6. (Example 1, Pages 10-11). Bartz further discloses concentration ranges of 2-8 parts by weight of taurine and 2 to 50 g amino acids/L ranges that overlap with the claims herein. The osmotic pressure of the solution was disclosed as 500 mOsm/l. (Example 1, Page 11). Bartz et. al. further discloses that the solution can have pH in the 5.5 to 6.5 range. (Page 9, Paragraph 4). Taurine (4.9 g/l) falls within the range of 0.01 to 5 w/v% claimed herein. The addition of electrolytes containing sodium, potassium, calcium or magnesium ions is disclosed. (Page 7, last paragraph). Preferred ion concentrations of 125 to 150 mmol/l of sodium ion, 0.5 to 2 mmol/l calcium ion and 0 to 2.5 mmol/l of magnesium ion. Note that mEq/L

and mmol/l are the same for monovalent ions such as sodium. For divalent ions, such as calcium and magnesium mEq/l is calculated by dividing mmol/l by two. Note that the recitation, "a peritoneal dialysate" is considered the intended use of the composition. Note that it is well settled that "intended use" of a composition or product, e.g., "peritoneal dialysate", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. Applicants argue that Bartz et. al. discloses a mixture of amino acids where taurine is only one of them. This argument was found unpersuasive since the claims herein use the open transitional phrase "containing" which allows the inclusion of other ingredients. Applicants further argue that Bartz et. al. dilutes the concentrate in example 1 from 0.49% taurine to 0.064% final concentration. However, the concentrate itself reads on the claims herein. As noted above, the recitation, "a peritoneal dialysate" is considered the intended use of the composition. Note that it is well settled that "intended use" of a composition or product, e.g., "peritoneal dialysate", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack*

114, USPQ 161. As such, the rejection under 102(b) is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-5, 7-10, 12-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartz et. al. (AU 615553; Of Record).

The disclosure of Bartz et. al. is discussed above.

Bartz et. al. does not exemplify a composition within the pH ranges of 6.0 to 7.5 or the particular concentration of 25 to 45 mEq/L of sodium lactate or a concentration of taurine in the range of 0.5 to 1.5% w/v%.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make peritoneal dialysate composition containing taurine, sodium lactate, sodium ion, calcium ion, magnesium ion, chloride ion and glucose having a pH of 6.0 to 7.5 because Bartz et. al. broadly discloses dialysates for intraperitoneal administration comprising the same ingredients ranges falling within or similar to the compositions claimed herein. Furthermore, it is expected that the solution of Bartz et. al. will achieve physiological pH range "upon use" overlapping the claimed

range herein. Bartz further discloses concentration ranges of 2-8 parts by weight of taurine and 2 to 50 g amino acids/L ranges that overlap with the claims herein. One of ordinary skill in the art would have been motivated to make a compositions containing taurine, sodium lactate, sodium ion, calcium ion, magnesium ion, chloride ion and glucose having a pH of 6.0 to 7.5 because Bartz et. al. broadly discloses dialysates for intraperitoneal administration comprising the same ingredients ranges falling within or similar to the compositions claimed herein. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Note that it is well settled that, merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (C.C. P.A. 1937). *In re Russell*, 439 F.2d 1228, 169 U.S. P.Q. 426 (C.C. P.A 1971). As such, claims 1, 5 and 7 are deemed anticipated by Bartz et. al. Therefore, one of ordinary skill in the art would have reasonably expected that the compositions of the instant application would have had substantially similar of better effects. If the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exits. See *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir 1990). See MPEP § 2144.05 [4-1]. Thus, the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. Applicants argue that there is no reason for one of ordinary skill in the art to drop the other 10 amino acids which form an essential part of the composition described in Bartz. However, the claims herein use the open transitional phrase "containing" which allows the inclusion of other ingredients. As such, the rejection under section 103(a) is still deemed proper and is adhered to.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number:
10/520,243
Art Unit: 1623

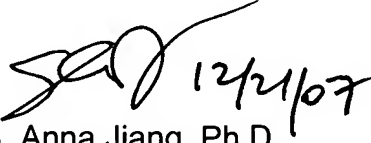
Page 8

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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